PSJ3

Exhibit 667A

Distributor Briefing

Wal-Mart Warehouse #45

August 19, 2015

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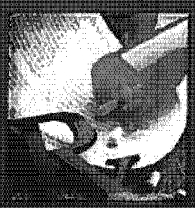
PowerPoint

Distributor Briefing

Wal-Mart Warehouse #15

August 14, 2015



Distributor Initiative

Educate and inform distributors of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances.

August 2005 – Present: Briefings to 84 firms with 279 registrations.

Briefing Overview

- Prescription Epidemic
- Closed System of Distribution
- Your Responsibilities
  - Suspicious Orders
  - "Know your Customer"
  - [illegible]
  - Your data
- Summary, including resources

Compliance with the CSA

This presentation does not cover the totality of your obligations nor is it a substitute for your obligations as a DEA registrant under the Controlled Substances Act and its implementing regulations.

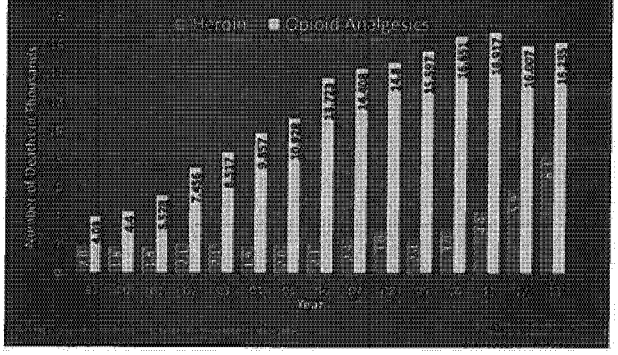
Compliance with the CSA

The information presented should not be considered new information. The substance of this presentation has been previously available and communicated through the Controlled Substances Act, its regulations, Federal Register Notices, DEA-sponsored conferences, correspondence from the DEA, and releases from the popular press, as well as your own sales data.

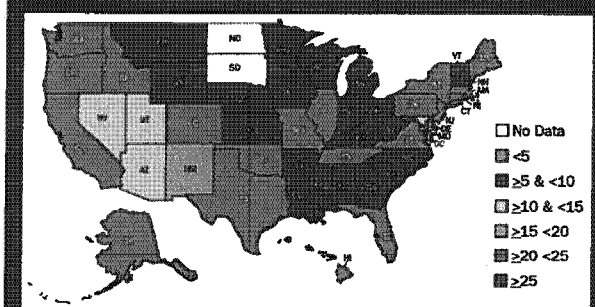
Top 10 List

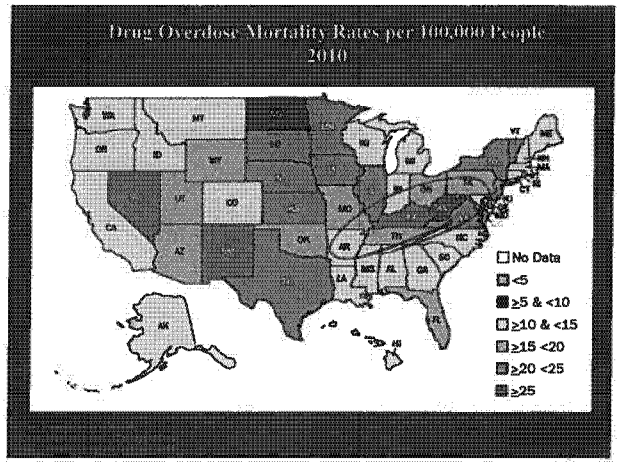
10 Guatemala	10 kilograms
09 India	10 kilograms
08 Vietnam	20 kilograms
07 China	20 kilograms
06 Denmark	25.5 kilograms
05 Colombia	50 kilograms
04 Syrian Republic	50 kilograms
03 Canada	115.5 kilograms
02 United Kingdom	200 kilograms
01 United States	79,700 kilograms 99.3%

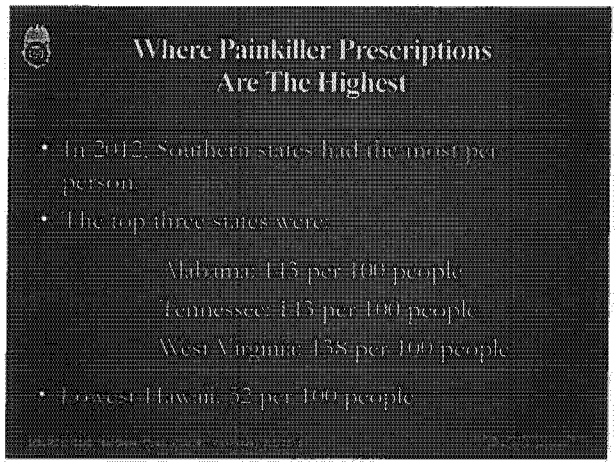
Drug-Poisoning Deaths Involving Opioid Analgesics or Heroin in the US, 1999-2013

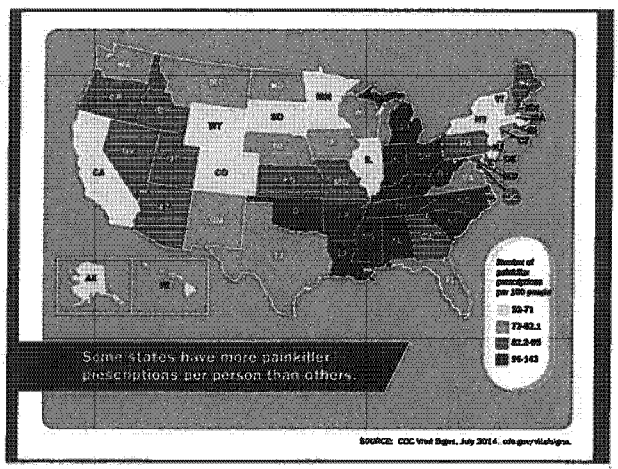


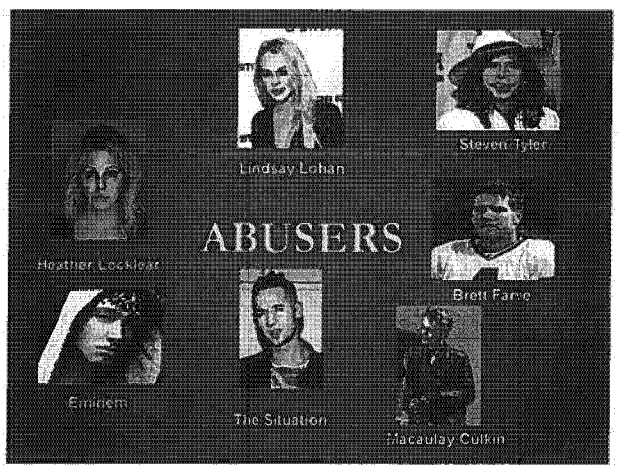
Drug Overdose Mortality Rates per 100,000 People 1999



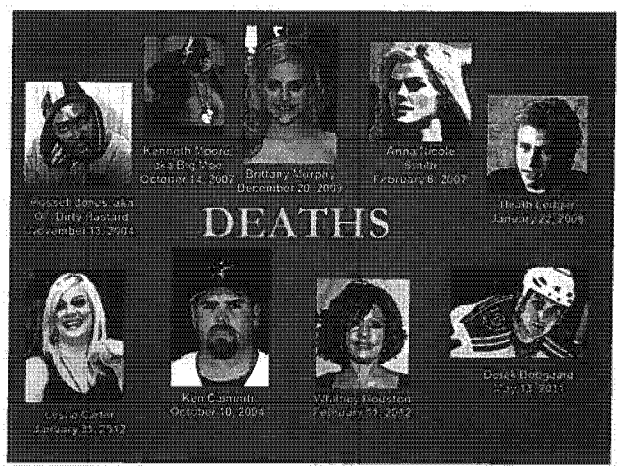

Drug Overdose Mortality Rates per 100,000 People
2010
No Data
<5
≥5 & <10
≥10 & <15
≥15 <20
≥20 <25
≥25


Where Painkiller Prescriptions Are The Highest
• In 2012, Southern states had the most per person.
• The top three states were:
Alabama: 116 per 100 people
Tennessee: 115 per 100 people
West Virginia: 138 per 100 people
• Lowest: Hawaii: 52 per 100 people


Some states have more painkiller prescriptions per person than others.


ABUSERS
Lindsay Lohan
Steven Tyler
Heather Locklear
Brett Favre
Eminem
The Situation
Macaulay Culkin

Illegitimate → tries everything/tried to relieve pain
Illegitimate → give prescriptions for cash



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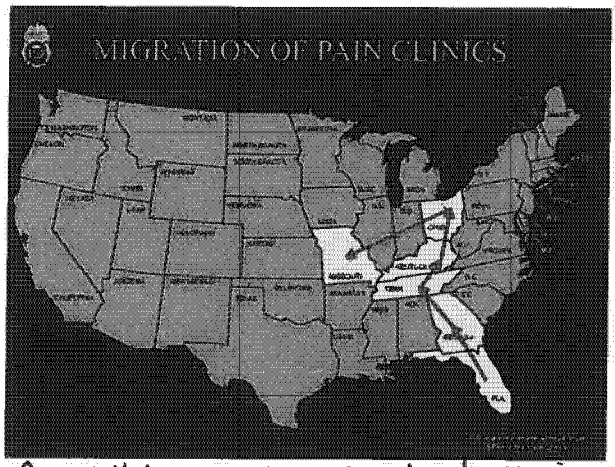
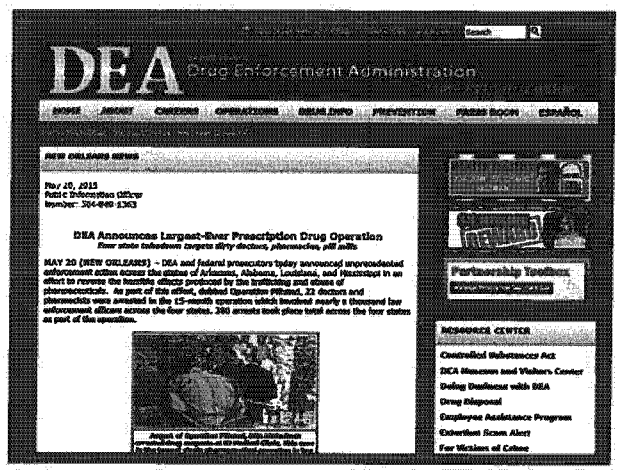
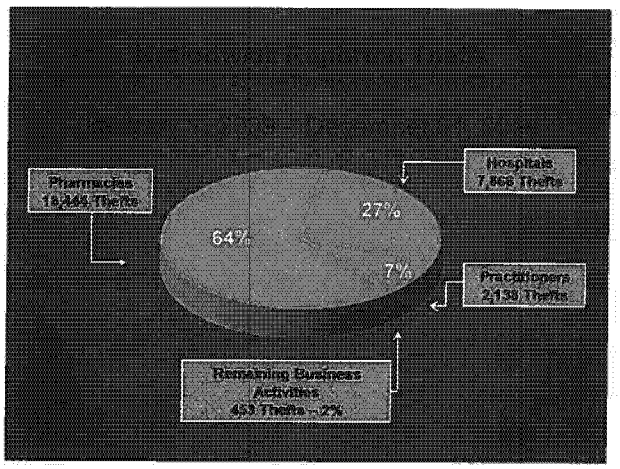
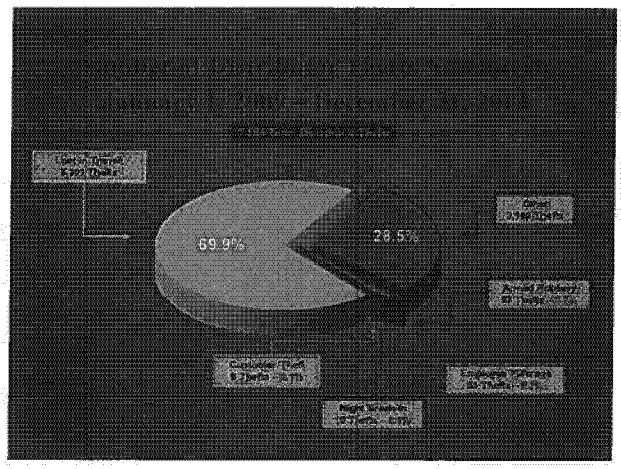


Seeing KY patients going to docs in GA & fill in AR bc AR PMP fairly new.







The Controlled Substances Act

Checks and Balances

Mission

The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

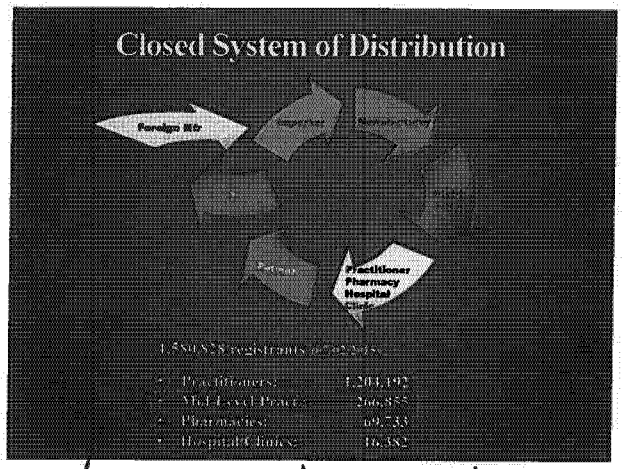
while

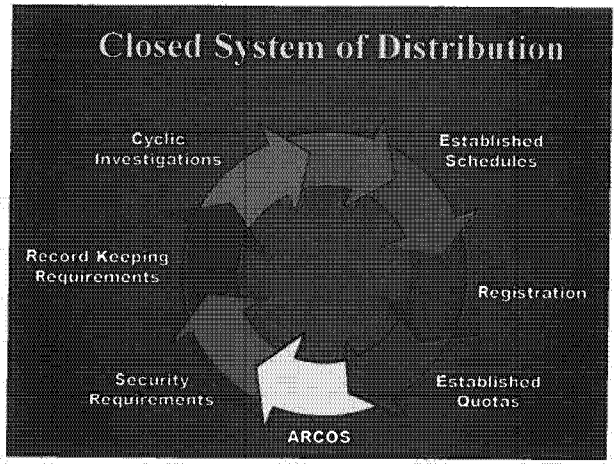
ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs

Closed System of Distribution

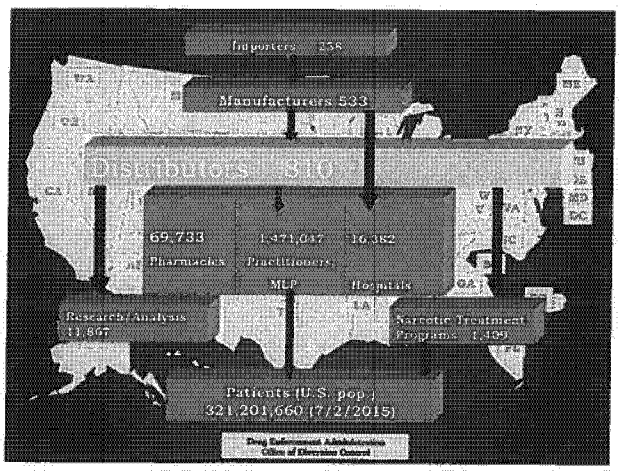
The DEA is responsible for:

- the oversight of the system
- the integrity of the system
- the protection of the public health and safety





↓Increasing but no data that should be more concerned about mid-level



Effective Controls

21 CFR § 1301.71(a):

All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

Effective Controls

21 CFR § 1301.71(a):

In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.

Reports: Non-Practitioners

21 CFR § 1301.74(b):

- The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances.
- The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.

Suspicious Orders Include

21 CFR 1301.74(b):

- Orders of unusual size
- Orders deviating substantially from a normal pattern
- Orders of unusual frequency

These criteria are disjunctive (they can stand alone or together).

Suspicious Orders

Reporting of a suspicious order to the DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion.

Suspicious Orders

The responsibility for making the decision to ship or not to ship rests with the supplier.

Once a Suspicious Order is identified by the supplier the order must **not** be shipped.

Suspicious Orders

The DEA will no longer accept "Excessive" Purchase Reports.

"Excessive" purchases were reported after the order had been filled.

Who are your Customers?

Practitioners

21 CFR § 1306.04(a):

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

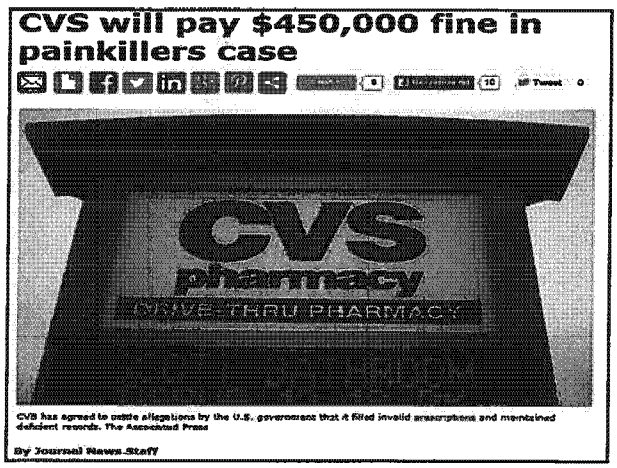
[illegible]

Pharmacies

"[T]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

Corresponding Responsibility

- A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate
- Just because a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription.



Pharmacies

- CVS
  - Filled invalid prescriptions; "corresponding responsibility"; failure to maintain accurate records
- S&S Pharmacy
  - Knowingly filled invalid prescriptions

Cardinal Health settles drug distribution case

By Donna Leinwand Leger, USA TODAY

The DEA suspended Cardinal Health, the country's second-largest drug distributor, from selling and shipping powerful painkillers and other drugs from its Lakeland, Fla., facility for two years as part of a settlement reached Tuesday.

Outside Cardinal Health headquarters in Dublin, Ohio.

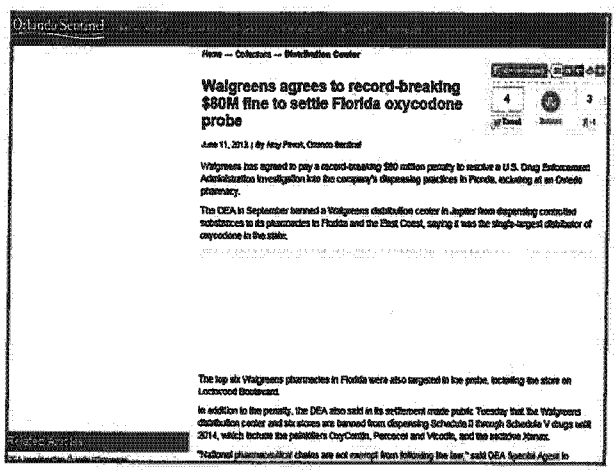
Sponsored Links

Travel Guard® Insurance

The Drug Enforcement Administration sought to revoke Cardinal's license in February, accusing the company of selling excessive amounts — more than 12 million oxycodone pain pills — to four Florida pharmacies over three years. The DEA said the company did not report suspicious orders or visit the chain pharmacies that purchased large amounts of the drugs.

The DEA also suspended controlled substances licenses for two CVS pharmacies in Sanford, Fla., which purchased millions of oxycodone pills from Cardinal. A judge is expected to rule on the CVS case this month.

"Cardinal Health is not above the law," said Joe Rannazzisi, DEA deputy assistant administrator. "With this agreement, it admits that it neglected its vital



Orlando Sentinel

Walgreens agrees to record-breaking $80M fine to settle Florida oxycodone probe

June 11, 2013 | By Amy Pavuk, Orlando Sentinel

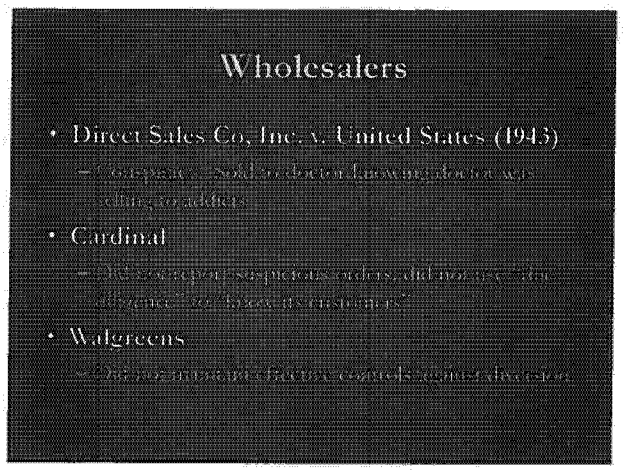
Walgreens has agreed to pay a record-breaking $80 million penalty to resolve a U.S. Drug Enforcement Administration investigation into the company's dispensing practices in Florida, including at an Orlando pharmacy.

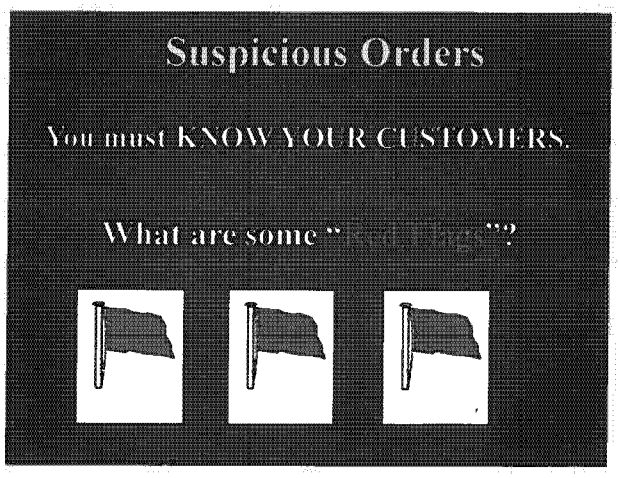
The DEA in September banned a Walgreens distribution center in Jupiter from dispensing controlled substances to its pharmacies in Florida and the East Coast, saying it was the single-largest distributor of oxycodone in the state.

The top six Walgreens pharmacies in Florida were also targeted in the probe, including the store on Lockwood Boulevard.

In addition to the penalty, the DEA also said in its settlement made public Tuesday that the Walgreens distribution center and six stores are banned from dispensing Schedule II through Schedule V drugs until 2014, which include the painkillers OxyContin, Percocet and Vicodin, and the sedative Xanax.

"National pharmaceutical chains are not exempt from following the law," said DEA Special Agent in





Know Your Customers

Some factors to consider when distributing controlled substances:

- Who is the purchaser?
- Where are they going?
- How many other distributors are involved?
- Who are the downstream customers?

Know Your Customers

- Type and quantity of controlled substances being purchased
- Location and hours of operation
- Methods of payment utilized (cash, credit card, insurance)
- % controlled vs. % non-controlled

Know Your Customers

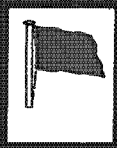
- What is the average monthly purchase for an average type of registrant for a particular controlled substance? For a particular geographical area?
- Does the requested purchase represent a quantity that far exceeds that average monthly purchase? Why?

Know Your Customers

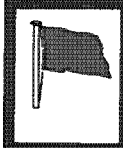
- What do media reports say about the state or geographical area where the controlled substances are being sold?
- Is there a problem with controlled substances in that particular area? What controlled substances are involved?

Know Your Customers

- Is a large portion of the CS prescriptions filled at a pharmacy for large quantities and paid for in cash or by credit card?
- Are the prescriptions mostly for opioids (hydrocodone, oxycodone), benzodiazepines (lorazepam, Ativan, diazepam), and muscle relaxers (Soma, Flexeril) prescribed together?



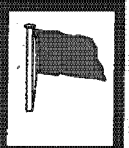
Know Your Customers



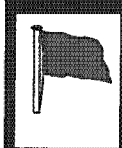
- Practitioner tells patients to fill their prescriptions at a specific pharmacy.
- The majority of the controlled substances prescriptions presented originated from the same practitioner.

Know Your Customers

- Many patients have identical prescriptions, (same drug, quantity, and strength) regardless of age, sex, or health.
- Patients of the same practitioner arrive at the pharmacy in groups with prescriptions for the same controlled substances.

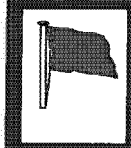


Know Your Customers

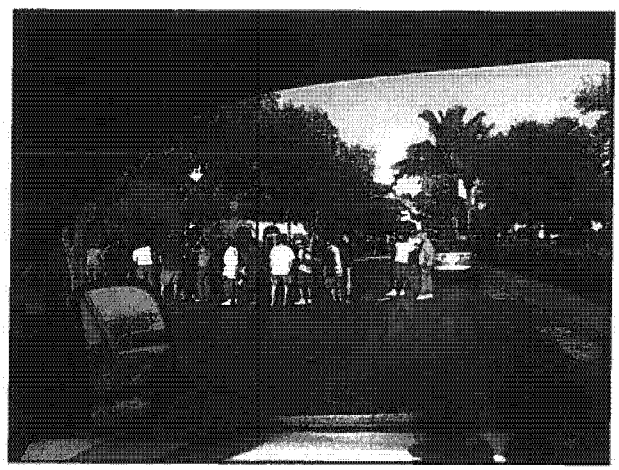


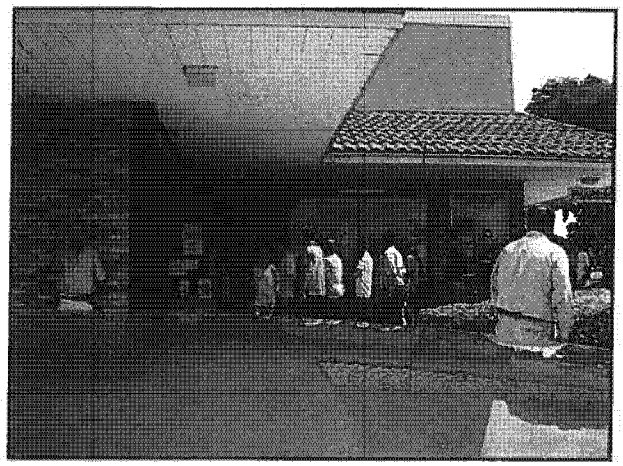
- Patients traveling great distances
- Prescriptions are pre-printed with the same diagnosis code
- Prescriptions are pre-printed with the same controlled substance

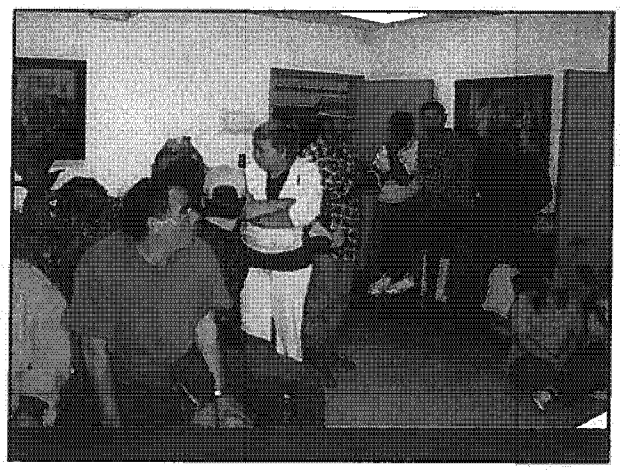
Know Your Customers



- Are there security guards on the premises? Why?
- Is there a line of people waiting to get into the place?
- Are there pain clinics in the area? How many? Is the pharmacy inside a pain clinic?







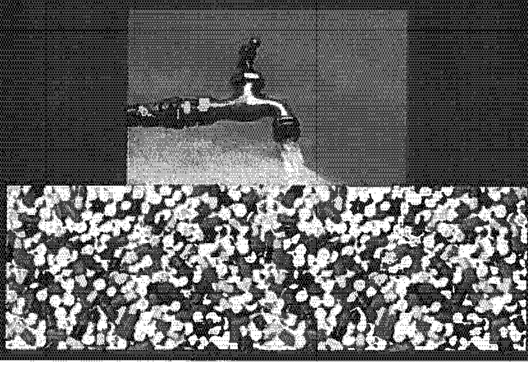
Closed System of Distribution

When a registrant fails to adhere to its responsibilities, those violations represent a danger to the public and jeopardize the closed system of distribution.

Closed System of Distribution

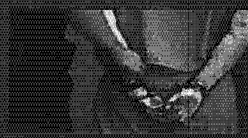
The listed examples of "Red Flags" should not be considered all-inclusive. Each customer and situation should be looked at independently.

Cutting off the Source of Supply



DEA Legal Recourse

- Administrative
  - Immediate Suspension Order (ISO)
  - Memorandum of Agreement (MOA)
  - Order to Show Cause (OTSC)
- Civil
  - Fines
- Criminal
  - Arrests
  - Criminal fines



The Order to Show Cause Process 21 USC § 824

Basis for Issuance

1. Falsification of application
2. Felony conviction
3. State license or registration suspended, revoked or denied – no longer authorized by State law
4. Inconsistent with public interest
5. Excluded from participation in Title 42 USC § 1320a-7(a) program

Immediate Suspension Order

Immediately suspend a registration upon a finding of imminent danger to public health and safety (Order to Show Cause served simultaneously)

Administrative Actions

Distributors only

(January 1, 2007, to June 30, 2015):

- Letters of Admonition 363
- Memoranda of Agreement 32
- Administrative Hearings 8
- Surrenders for Cause 46
- Immediate Suspension 16
- Order to Show Cause Issued 16

Did we ever get anything from 6028

Civil Action - Distributor Registrants

- August 2005 – Present:
- Civil action against 35 distributor registrations:
  - Over $187 million in civil fines
- These were negotiated settlements

Company Data

The following charts and graphs have been compiled from ARCOS reports your firm has previously submitted to DEA. The data was reviewed and the purchases of a few of your customers will be addressed during our discussion.

The mentioning of specific customers is NOT to be implied that the sale of controlled substances to these customers is illicit or that they may be involved in illicit activities.

It also should NOT be inferred that based upon the documentation provided to you that your company should terminate or restrict business with any customer discussed for the purposes of this presentation.

It is incumbent upon you to know your customers, fully review all orders for controlled substances, and to exercise due diligence procedures prior to deciding whether or not to terminate or restrict sales to any customer.

Summary

- Prescriptions that are not written in the usual course of professional practice are not valid
- Controlled substances dispensed pursuant to invalid prescriptions or not for a legitimate medical purpose are being diverted from the legitimate channel of distribution
- Not limited to internet pharmacy

Summary

- A pattern of controlled substances being distributed by a distributor to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor
- The DEA registration of the distributor could be revoked under public interest grounds

Summary

- A distributor who is selling controlled substances that are being dispensed outside the usual course of professional practice must stop immediately
- DEA cannot guarantee that past failure to maintain effective controls against diversion will not result in action against a distributor

Fentanyl

Regulatory Section (ODG)

- Registration (DEA number) validation
- Federal Register notices (e.g. change of schedule)
- ARCOS
- Publications and Manuals
- DEA forms including 222, 222a, and 106
- Contact information for local DEA offices

Regulatory Section (ODG)

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Michele Herron, Unit Chief (ODGR)
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Abby Hayes, Staff Coordinator
202-307-8940
Inez Davis, Staff Coordinator
202-598-8379

Documentation for prescriptions
→ Note on prescription

For Suspicious Order
→ On site visits
→ Contacted store
→ Does pharmacy support those types of numbers

Documentation
→ No standards but documentation is good "Proof"

17

U.S.C. Cites

21 USC 823: Registration requirements
Text contains those laws in effect on August 11, 2015

From Title 21-FOOD AND DRUGS
CHAPTER 13-DRUG ABUSE PREVENTION AND CONTROL
SUBCHAPTER I-CONTROL AND ENFORCEMENT
Part C-Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

Jump To:

§823. Registration requirements

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any

controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards

established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

(iii) The total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The Secretary may by regulation change such total number.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or section 262 of title 42, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f) of this section.

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f) of this section.

(ii) Upon receiving a notification under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f) of this section. The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such

drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term "group practice" has the meaning given such term in section 1395nn(h)(4) of title 42.

(ii) The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to

exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.

(I) During the 3-year period beginning on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs, to patients for maintenance or detoxification treatment in accordance with this paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug.[1]

(J)(i) This paragraph takes effect on the date referred to in subparagraph (I), and remains in effect thereafter.

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on December 29, 2006, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being dispensed or possessed in violation of this chapter; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 802(39)(A) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider-

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(Pub. L. 91–513, title II, §303, Oct. 27, 1970, 84 Stat. 1253 ; Pub. L. 93–281, §3, May 14, 1974, 88 Stat. 124 ; Pub. L. 95–633, title I, §109, Nov. 10, 1978, 92 Stat. 3773 ; Pub. L. 98–473, title II, §511, Oct. 12, 1984, 98 Stat. 2073 ; Pub. L. 103–200, §3(c), Dec. 17, 1993, 107 Stat. 2336 ; Pub. L. 106–310, div. B, title XXXV, §3502(a), Oct. 17, 2000, 114 Stat. 1222 ; Pub. L. 107–273, div. B, title II, §2501, Nov. 2, 2002, 116 Stat. 1803 ; Pub. L. 109–56, §1(a), (b), Aug. 2, 2005, 119 Stat. 591 ; Pub. L. 109–177, title VII, §712(a)(3), Mar. 9, 2006, 120 Stat. 263 ; Pub. L. 109–469, title XI, §1102, Dec. 29, 2006, 120 Stat. 3540 ; Pub. L. 110–425, §3(b), Oct. 15, 2008, 122 Stat. 4824 .)

REFERENCES IN TEXT

Schedules I, II, III, IV, and V, referred to in subsecs. (a) to (f) and (g)(2), are set out in section 812(c) of this title.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(2)(C)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This chapter, referred to in subsec. (g)(2)(J)(ii)(II), was in the original "this Act", meaning Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1236 , as amended. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

2008-Subsec. (f). Pub. L. 110–425, in introductory provisions, inserted "and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet" after "schedule II, III, IV, or V" and substituted "or such modification of registration if the Attorney General determines that the issuance of such registration or modification" for "if he determines that the issuance of such registration".

2006-Subsec. (g)(2)(B)(iii). Pub. L. 109–469, §1102(1), substituted "unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The" for "except that the".

Subsec. (g)(2)(J)(i). Pub. L. 109–469, §1102(2)(A), substituted "thereafter." for "thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect)."

Subsec. (g)(2)(J)(ii). Pub. L. 109–469, §1102(2)(B), substituted "December 29, 2006" for "October 17, 2000" in introductory provisions.

Subsec. (g)(2)(J)(iii). Pub. L. 109–469, §1102(2)(C), substituted "subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective" for "this paragraph should not remain in effect, this paragraph ceases to be in effect".

Subsec. (h). Pub. L. 109–177 substituted "clause (iv) or (v) of section 802(39)(A) of this title" for "section 802(39)(A)(iv) of this title" in introductory provisions.

2005-Subsec. (g)(2)(B)(iii). Pub. L. 109–56, §1(b), substituted "The total" for "In any case in which the practitioner is not in a group practice, the total".

Subsec. (g)(2)(B)(iv). Pub. L. 109–56, §1(a), struck out cl. (iv) which read as follows: "In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have."

2002-Subsec. (g)(2)(I). Pub. L. 107–273, §2501(1), which directed the substitution of "on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs," for "on October 17, 2000, a State may not preclude a practitioner from dispensing or prescribing drugs in schedule III, IV, or V, or combinations of such drugs,", was executed by making the substitution for the phrase which in the original began with "on the date of the enactment of the Drug Addiction Treatment Act of 2000," rather than the editorial translation "on October 17, 2000," to reflect the probable intent of Congress.

Subsec. (g)(2)(J)(i). Pub. L. 107–273, §2501(2), which directed the substitution of "the date referred to in subparagraph (I)," for "October 17, 2000," was executed by making the

substitution for text which in the original read "the date of the enactment of the Drug Addiction Treatment Act of 2000," rather than the editorial translation "October 17, 2000," to reflect the probable intent of Congress.

2000-Subsec. (g). Pub. L. 106–310 designated existing provisions as par. (1), substituted "Except as provided in paragraph (2), practitioners who dispense" for "Practitioners who dispense", redesignated former pars. (1) to (3) as subpars. (A) to (C), respectively, of par. (1) and redesignated former subpars. (A) and (B) of former par. (2) as cls. (i) and (ii), respectively, of subpar. (B) of par. (1), and added par. (2).

1993-Subsec. (h). Pub. L. 103–200 added subsec. (h).

1984-Subsec. (f). Pub. L. 98–473 amended subsec. (f) generally, substituting provisions relating to registration authority of Attorney General respecting dispensation or conduct of research with controlled research, and separate authority of Secretary respecting registration, for provisions relating to general registration requirements respecting dispensation or conduct of research with controlled or nonnarcotic controlled substances.

1978-Subsec. (f). Pub. L. 95–633 inserted provision relating to the construction of the Convention on Psychotropic Substances.

1974-Subsec. (g). Pub. L. 93–281 added subsec. (g).

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110–425, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–56, §1(c), Aug. 2, 2005, 119 Stat. 591 , provided that: "This section [amending this section] shall take effect on the date of enactment of this Act [Aug. 2, 2005]."

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

PROVISIONAL REGISTRATION

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, Internal Revenue Code, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

[1] *So in original. Probably should be "combinations of drugs.".*

21 USC 824: Denial, revocation, or suspension of registration
Text contains those laws in effect on August 11, 2015

From Title 21-FOOD AND DRUGS
CHAPTER 13-DRUG ABUSE PREVENTION AND CONTROL
SUBCHAPTER I-CONTROL AND ENFORCEMENT
Part C-Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances
Jump To:

§824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant-

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42.

A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(d) Suspension of registration in cases of imminent danger

The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g)(1) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including

judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(e) Suspension and revocation of quotas

The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 826 of this title.

(f) Disposition of controlled substances or list I chemicals

In the event the Attorney General suspends or revokes a registration granted under section 823 of this title, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 881(e) of this title. All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) Seizure or placement under seal of controlled substances or list I chemicals

The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

(Pub. L. 91–513, title II, §304, Oct. 27, 1970, 84 Stat. 1255 ; Pub. L. 93–281, §4, May 14, 1974, 88 Stat. 125 ; Pub. L. 98–473, title II, §§304, 512, 513, Oct. 12, 1984, 98 Stat. 2050 , 2073; Pub. L. 100–93, §8(j), Aug. 18, 1987, 101 Stat. 695 ; Pub. L. 103–200, §3(d), Dec. 17, 1993, 107 Stat. 2337 ; Pub. L. 103–322, title XXXIII, §330024(e), Sept. 13, 1994, 108 Stat. 2151 ; Pub. L. 106–310, div. B, title XXXV, §3502(b), Oct. 17, 2000, 114 Stat. 1227 .)

REFERENCES IN TEXT

This subchapter, referred to in subsec. (a)(1), (2), was in the original "this title", meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242 , as amended, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Subchapter II of this chapter, referred to in subsec. (a)(1), (2), was in the original "title III", meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285 . Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

AMENDMENTS

2000-Subsec. (a). Pub. L. 106–310, §3502(b)(1), substituted "section 823(g)(1) of this title" for "section 823(g) of this title" in two places in concluding provisions.

Subsec. (d). Pub. L. 106–310, §3502(b)(2), substituted "section 823(g)(1) of this title" for "section 823(g) of this title".

1994-Subsec. (g). Pub. L. 103–322 inserted "or chemical" after "such substance" in last sentence.

1993-Subsec. (a). Pub. L. 103–200, §3(d)(1), inserted "or a list I chemical" after "controlled substance" in introductory provisions and par. (2) and inserted "or list I chemicals" after "controlled substances" in par. (3).

Subsec. (b). Pub. L. 103–200, §3(d)(2), inserted "or list I chemical" after "controlled substance".

Subsec. (f). Pub. L. 103–200, §3(d)(3), inserted "or list I chemicals" after "controlled substances" wherever appearing.

Subsec. (g). Pub. L. 103–200, §3(d)(4), inserted "or list I chemicals" after "controlled substances" in two places and "or list I chemical" after "controlled substance" wherever appearing.

1987-Subsec. (a)(5). Pub. L. 100–93 added par. (5).

1984-Subsec. (a)(3). Pub. L. 98–473, §512(1), inserted provisions relating to suspension, etc., recommended by competent State authority.

Subsec. (a)(4). Pub. L. 98–473, §512(2), added par. (4).

Subsec. (f). Pub. L. 98–473, §304, inserted provisions relating to vesting of right, title, and interest in the United States.

Subsec. (g). Pub. L. 98–473, §513, added subsec. (g).

1974-Subsec. (a). Pub. L. 93–281, §4(a), provided for revocation or suspension of a registration pursuant to section 823(g) of this title for failure of a registrant to comply with standards referred to in such section 823(g).

Subsec. (d). Pub. L. 93–281, §4(b), substituted "A suspension under this subsection" for "Such suspension" in third sentence.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–322 effective 120 days after Dec. 17, 1993, see section 330024 (f) of Pub. L. 103–322, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by Pub. L. 100–93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100–93, set out as a note under section 1320a–7 of Title 42, The Public Health and Welfare.

PROVISIONAL REGISTRATION

Applicability of this section to provisional registrations, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

C.F.R. Cites

ELECTRONIC CODE OF FEDERAL REGULATIONS

e-CFR data is current as of August 10, 2015

Title 21 → Chapter II → Part 1301 → §1301.71

Title 21: Food and Drugs
PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

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§1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in §§1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems and/or combination lock control systems;

(9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and

(15) The applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in §§1301.72-1301.76 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§1301.72-1301.76 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Special Agent in Charge in the region in which the system will be used, or to the Regulatory Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(e) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in §§1301.72, 1301.73 and 1301.75. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Administration, shall not necessarily be deemed to comply substantially with the standards set forth in §§1301.72, 1301.73 and 1301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Administration.

(f) A collector shall not employ, as an agent or employee who has access to or influence over controlled substances acquired by collection, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for

registration with DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, "for cause" means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

[36 FR 18729, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 47 FR 41735, Sept. 22, 1982; 51 FR 5319, Feb. 13, 1986; 68 FR 41228, July 11, 2003; 75 FR 10677, Mar. 9, 2010; 79 FR 53561, Sept. 9, 2014]

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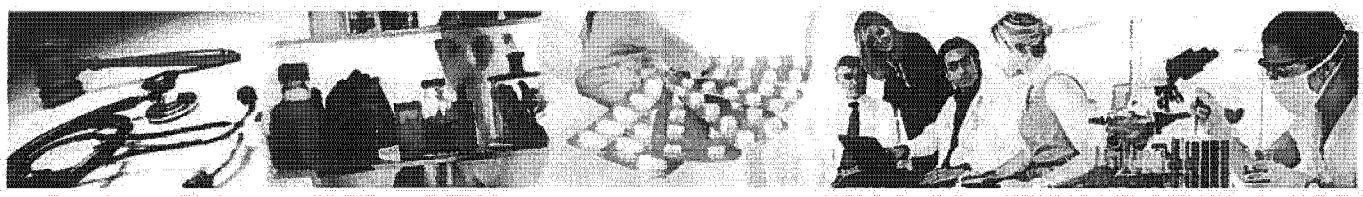

Title 21 Code of Federal Regulations

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

SECURITY REQUIREMENTS

§1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area , in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. The supplier is responsible for reporting all in-transit losses of controlled substances by the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of **part 1305** of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term "customer" includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in **Sec. 1301.72**. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

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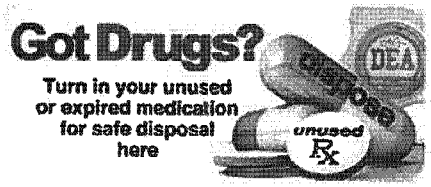
Title 21 Code of Federal Regulations
Title 21 USC Codified CSA

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

(m) A reverse distributor shall not employ, as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, "for cause" means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

[36 FR 7778, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

Editorial Note: For Federal Register citations affecting §1301.74, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.



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US v Moore

UNITED STATES *v.* MOORE

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 74-759. Argued October 7, 1975—Decided December 9, 1975

Respondent, a licensed physician registered under the Controlled Substances Act (CSA), 21 U. S. C. § 801 *et seq.*, was convicted of knowing and unlawful distribution and dispensation of methadone (a controlled substance or addictive drug used in the treatment of heroin addicts) in violation of 21 U. S. C. § 841 (a)(1), which makes it unlawful for "any person" knowingly or intentionally to distribute or dispense a controlled substance, except as authorized by the CSA. The evidence disclosed that respondent prescribed large quantities of methadone for patients without giving them adequate physical examinations or specific instructions for its use and charged fees according to the quantity of methadone prescribed rather than fees for medical services rendered. The Court of Appeals, however, reversed the conviction on the grounds that respondent was exempted from prosecution under § 841 by virtue of his status as a registrant and that a registrant can be prosecuted only under §§ 842 and 843, which prescribe less severe penalties than § 841. *Held:* Registered physicians can be prosecuted under § 841 when, as here, their activities fall outside the usual course of professional practice. Pp. 131–145.

(a) Only the lawful acts of registrants under the CSA are exempted from prosecution under § 841. That section by its terms reaches "any person" and does not exempt (as it could have) "all registrants" or "all persons registered under the Act." The language of the qualified authorization of § 822 (b), which authorizes registrants to possess, distribute, or dispense controlled substances to the extent authorized by their registration and in conformity with other CSA provisions, and which was added merely to ensure that persons engaged in lawful activities could not be prosecuted, cannot be fairly read to support the view that all activities of registered physicians are beyond the reach of § 841 simply because of their status. Pp. 131–133.

(b) There is no indication in the operative language of §§ 841–843 that Congress intended to establish two mutually exclusive

penalty systems, with nonregistrants to be punished under § 841 and registrants under §§ 842 and 843, the fact that the term "registrants" is used in some subsections of §§ 842 and 843 but not in § 841 being of limited significance. Moreover, the legislative history indicates that Congress was concerned with the nature of the drug transaction, rather than with the defendant's status. Pp. 133–135.

(c) It is immaterial whether respondent also could have been prosecuted for the relatively minor offense of violating § 829 with respect to the issuing of prescriptions, since there is nothing in the statutory scheme or the legislative history that justifies a conclusion that a registrant who may be prosecuted for violating § 829 is thereby exempted from prosecution under § 841 for the significantly greater offense of acting as a drug "pusher." Pp. 135–138.

(d) The scheme of the CSA, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his "professional practice." Pp. 138–143.

(e) Congress was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients, but it did not intend to exempt from serious criminal penalties those acts by physicians that go beyond the limits of approved professional practice. Pp. 143–145.

(f) Where the statutory purpose is clear, the canon of strict construction of criminal statutes favoring the accused will be satisfied if the words of the statute are "given their fair meaning in accord with the manifest intent of the lawmakers." *United States* v. *Brown*, 333 U. S. 18, 25–26. P. 145.

164 U. S. App. D. C. 319, 505 F. 2d 426, reversed and remanded.

POWELL, J., delivered the opinion for a unanimous Court.

Paul L. Friedman argued the cause for the United States. With him on the briefs were *Solicitor General Bork, Assistant Attorney General Thornburgh, Acting Assistant Attorney General Keeney,* and *Sidney M. Glazer.*

Raymond W. Bergan argued the cause for respond-

ent. With him on the brief were *Edward Bennett Williams* and *Harold Ungar*.

MR. JUSTICE POWELL delivered the opinion of the Court.

The issue in this case is whether persons who are registered under the Controlled Substances Act (CSA or Act), 84 Stat. 1242, 21 U. S. C. § 801 *et seq.*, can be prosecuted under § 841 for dispensing or distributing controlled substances. The United States Court of Appeals for the District of Columbia Circuit reversed the conviction of respondent, a licensed physician registered under the Act, on the ground that he was exempted from prosecution under § 841 by virtue of his status as a registrant. We reverse and hold that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice.

I

Dr. Moore was charged, in a 639-count indictment, with the knowing and unlawful distribution and dispensation of methadone (Dolophine), a Schedule II controlled substance,[1] in violation of 21 U. S. C. § 841 (a)(1). That subsection provides:

> "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—
>
> "(1) to manufacture, distribute, or dispense, or

[1] A substance listed in Schedule II has "a high potential for abuse," "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions," and is a drug the abuse of which "may lead to severe psychological or physical dependence." 21 U. S. C. § 812 (b)(2). Methadone is listed as a Schedule II drug in § 812 (c), Schedule II (b)(11).

possess with intent to manufacture, distribute, or dispense, a controlled substance . . . ."

The indictment covered a 5½-month period from late August 1971 to early February 1972. It was reduced before trial to 40 counts, and the jury convicted respondent on 22 counts. He was sentenced to concurrent terms of five to 15 years' imprisonment on 14 counts, and to concurrent terms of 10 to 30 years on the remaining eight counts. The second set of sentences was to be consecutive with the first. Fines totaling $150,000 were also imposed.[2]

Methadone is an addictive drug used in the treatment of heroin addicts. If taken without controls it can, like heroin, create euphoric "highs," but if properly administered it eliminates the addict's craving for heroin without providing a "high." The two principal methods of treating heroin addicts with methadone are "detoxification" and "maintenance." Under a maintenance program, the addict is given a fixed dose once a day for an indefinite period to keep him from using heroin. In detoxification the addict is given a large dose of methadone during the first few days of treatment to keep him free of withdrawal symptoms. Then the dose is gradually reduced until total abstinence is reached.

Maintenance is the more controversial method of treatment. During the period covered by the indictment, registration under § 822, in itself, did not entitle a physician to conduct a maintenance program. In addition to a § 822 registration, the physician who wished to conduct such a program was required to

[2] In addition, Dr. Moore's license to practice medicine was revoked pursuant to D. C. Code Ann. § 2–131 (1973), which authorizes revocation upon the conviction of "any felony." An appeal from the conviction acts "as a supersedeas to the judgment . . . revoking his license . . . ."

obtain authorization from the Food and Drug Administration for investigation of a new drug. Dr. Moore's authorization by the FDA was revoked in the summer of 1971, and he does not claim that he was conducting an authorized maintenance program. Instead, his defense at trial was that he had devised a new method of detoxification based on the work of a British practitioner. He testified that he prescribed large quantities of methadone to achieve a "blockade" condition, in which the addict was so saturated with methadone that heroin would have no effect, and to instill a strong psychological desire for detoxification. The Government's position is that the evidence established that Dr. Moore's conduct was inconsistent with all accepted methods of treating addicts, that in fact he operated as a "pusher."

Respondent concedes in his brief that he did not observe generally accepted medical practices. He conducted a large-scale operation. Between September 1971 and mid-February 1972 three District of Columbia pharmacies filled 11,169 prescriptions written by Dr. Moore. These covered some 800,000 methadone tablets. On 54 days during that period respondent wrote over 100 prescriptions a day. In billing his patients he used a "sliding-fee scale" pegged solely to the quantity prescribed, rather than to the medical services performed. The fees ranged from $15 for a 50-pill prescription to $50 for 150 pills. In five and one-half months Dr. Moore's receipts totaled at least $260,000.

When a patient entered the office he was given only the most perfunctory examination. Typically this included a request to see the patient's needle marks (which in more than one instance were simulated) and an unsupervised urinalysis (the results of which were regularly ignored). A prescription was then written for the amount requested by the patient. On return visits—for

which appointments were never scheduled—no physical examination was performed and the patient again received a prescription for whatever quantity he requested. Accurate records were not kept, and in some cases the quantity prescribed was not recorded. There was no supervision of the administration of the drug. Dr. Moore's instructions consisted entirely of a label on the drugs reading: "Take as directed for detoxification." Some patients used the tablets to get "high"; others sold them or gave them to friends or relatives. Several patients testified that their use of methadone increased dramatically while they were under respondent's care.[3]

The Court of Appeals, with one judge dissenting, assumed that respondent acted wrongfully but held that he could not be prosecuted under § 841.[4] 164 U. S.

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[3] One patient testified that he was taking approximately two to three pills per day when he started visiting Dr. Moore. By the end of his visits he was taking 30 to 35 pills a day. App. 43. Another patient increased his intake from five to 10 pills a day to almost 70. *Id.*, at 53–54. A third addict, relying on Dr. Moore for drugs, increased his intake from seven pills a day to over 100. Tr. 310.

[4] Section 841 (a) provides, in full:

"Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

"(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

"(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance."

"Dispense" is defined in § 802 (10) to mean "to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance . . . ." Section 802 (11) defines "distribute" to mean "to deliver (other than by administering or dispensing) a controlled substance." "Administer" refers to "the direct application of a controlled substance to the body of a patient . . . ." § 802 (2).

App. D. C. 319, 505 F. 2d 426 (1974). The court found that Congress intended to subject registered physicians to prosecution only under §§ 842 and 843,[5] which pre-

[5] Section 842 in relevant part provides:

"(a) Unlawful acts.

"It shall be unlawful for any person—

"(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title;

"(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

"(3) who is a registrant to distribute a controlled substance in violation of section 825 of this title;

"(4) to remove, alter, or obliterate a symbol or label required by section 825 of this title;

"(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;

"(6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II of this chapter;

"(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 824 (f) or 881 of this title or to remove or dispose of substances so placed under seal; or

"(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II of this chapter, any information acquired in the course of an inspection authorized by this subchapter concerning any method or process which as a trade secret is entitled to protection.

"(b) Manufacture.

"It shall be unlawful for any person who is a registrant to manufacture a controlled substance in Schedule I or II which is—

"(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 826 of this title; or

"(2) in excess of a quota assigned to him pursuant to section 826 of this title."

[*Footnote 5 is continued on p. 129*]

scribe less severe penalties than § 841.[6] The court reasoned:

". . . Congress intended to deal with registrants pri-

Section 843 provides:

"(a) Unlawful acts.

"It shall be unlawful for any person knowingly or intentionally—

"(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as required by section 828 of this title;

"(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

"(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

"(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II of this chapter; or

"(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance.

"(b) Communication facility.

"It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this subchapter or subchapter II of this chapter. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term 'communication facility' means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication."

[6] Violations of § 841, under which respondent was convicted, carry sentences of up to 15 years, fines as high as $25,000,

> marily through a system of administrative controls, relying on modest penalty provisions to enforce those controls, and reserving the severe penalties provided for in § 841 for those seeking to avoid regulation entirely by not registering." 164 U. S. App. D. C., at 323, 505 F. 2d, at 430.

It said, further, that §§ 842 and 843 were enacted to enforce that scheme, while § 841 was reserved for prosecution of those outside the "legitimate distribution chain." Persons registered under the Act were "authorized by [the] subchapter" within the meaning of § 841 and thus were thought to be immunized against prosecution under that section.[7]

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or both. § 841 (b). Knowing violators of § 842 are subject at most to imprisonment for one year, a fine of $25,000, or both. There also may be a civil penalty of $25,000 for violation of § 842. § 842 (c). The penalties for violation of § 843 are imprisonment for not more than four years, a fine of not more than $30,000, or both. § 843 (c). All three sections impose higher penalties for violations after the first conviction.

[7] The decision below stands alone. At the time it was issued it conflicted with the rulings of four other Circuits. Courts of Appeals for the First, Fifth, and Tenth Circuits had held squarely that physicians may be prosecuted under § 841. See *United States* v. *Badia*, 490 F. 2d 296 (CA1 1973); *United States* v. *Collier*, 478 F. 2d 268 (CA5 1973); *United States* v. *Leigh*, 487 F. 2d 206 (CA5 1973); *United States* v. *Bartee*, 479 F. 2d 484 (CA10 1973); *United States* v. *Jobe*, 487 F. 2d 268 (CA10 1973). The Ninth Circuit also had affirmed the conviction of a physician under § 841 (a)(1). *United States* v. *Larson*, 507 F. 2d 385 (1974). Since the ruling in this case, two other decisions have considered the issue and expressly rejected the analysis of the Court of Appeals for the District of Columbia Circuit. See *United States* v. *Rosenberg*, 515 F. 2d 190 (CA9 1975); *United States* v. *Green*, 511 F. 2d 1062 (CA7 1975). The Sixth Circuit has implicitly agreed. It reversed the conviction of a physician and remanded the case for a new trial because the trial court had failed to instruct the jury that physicians are exempt from prosecution under § 841 (a)(1) when they dispense or prescribe controlled substances in good faith to patients in the regular course of

Respondent advances two basic arguments, contending that each requires affirmance of the Court of Appeals: (i) as that court held, registered physicians may be prosecuted only under §§ 842 and 843; and (ii) in any event, respondent cannot be prosecuted under § 841 because his conduct was "authorized by [the] subchapter" in question. We now consider each of these arguments.

II

A

Section 841 (a)(1) makes distribution and dispensing of drugs unlawful "[e]xcept as authorized by this subchapter . . . ." Relying on this language, the Court of Appeals held that a physician registered under the Act is *per se* exempted from prosecution under § 841 because of his status as a registrant. We take a different view and hold that only the lawful acts of registrants are exempted. By its terms § 841 reaches "any person." It does not exempt (as it could have) "all registrants" or "all persons registered under this Act."

The Court of Appeals relied also on § 822 (b), which provides: "Persons registered . . . under this subchapter to . . . distribute, or dispense controlled substances are authorized to possess, . . . distribute, or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." This is a qualified authorization of certain activities, not a blanket authorization of all acts by certain persons. This limitation is emphasized by the subsection's heading "Authorized activities," which parallels the headings of §§ 841–843 "Unlawful acts." We think the statutory language cannot fairly be read to support the view that all activities of registered physi-

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professional practice. *United States* v. *Carroll*, 518 F. 2d 187 (1975).

cians are exempted from the reach of § 841 simply because of their status.

If § 822 (b) were construed to authorize all such activities, thereby exempting them from other constraints, it would constitute a sharp departure from prior laws. But there is no indication that Congress had any such intent. Physicians who stepped outside the bounds of professional practice could be prosecuted under the Harrison Act (Narcotics) of 1914, 38 Stat. 785, the predecessor of the CSA. In *Jin Fuey Moy* v. *United States*, 254 U. S. 189 (1920), the Court affirmed the conviction of a physician on facts remarkably similar to those before us (*e. g.*, no adequate physical examination, the dispensing of large quantities of drugs without specific directions for use, and fees graduated according to the amount of drugs prescribed). A similar conviction was upheld in *United States* v. *Behrman*, 258 U. S. 280 (1922), where the defendant-doctor had prescribed heroin, morphine, and cocaine to a person whom he knew to be an addict.

In enacting the CSA Congress attempted to devise a more flexible penalty structure than that used in the Harrison Act. H. R. Rep. No. 91–1444, Pt. 1, pp. 1, 4 (1970).[8] Penalties were geared to the nature of the violation, including the character of the drug involved. But the Act was intended to "strengthen," rather than to weaken, "existing law enforcement authority in the field of drug abuse." 84 Stat. 1236 (1970) (preamble). See also H. R. Rep. No. 91–1444, p. 1.

Section 822 (b) was added to the original bill at a late date [9] to "make it clear that persons registered under

[8] To this end controlled substances were classified in five categories according to their potential for abuse, their promise for treatment, and their psychological and physical effects. § 812.

[9] Section 822 (b) was added by the House Committee on Interstate and Foreign Commerce. No comparable section was in the Act when it passed the Senate on January 28, 1970.

this title are authorized to deal in or handle controlled substances." H. R. Rep. No. 91–1444, p. 38. It is unlikely that Congress would seek, in this oblique way, to carve out a major new exemption, not found in the Harrison Act, for physicians and other registrants. Rather, § 822 (b) was added merely to ensure that persons engaged in lawful activities could not be prosecuted.

B

Respondent nonetheless contends that §§ 841 and 822 (b) must be interpreted in light of a congressional intent to set up two separate and distinct penalty systems: Persons not registered under the Act are to be punished under § 841, while those who are registered are to be subject only to the sanctions of §§ 842 and 843. The latter two sections, the argument goes, establish modest penalties which are the sole sanctions in a system of strict administrative regulation of registrants.

The operative language of those sections provides no real support for the proposition that Congress intended to establish two mutually exclusive systems. It is true that the term "registrants" is used in §§ 842 and 843, and not in § 841. But this is of limited significance. All three sections provide that "[i]t shall be unlawful for any person . . . [to commit the proscribed acts]." Two of the eight subsections of § 842 (a), one of the five subsections of § 843 (a), and § 842 (b) further qualify "any person" with "who is a registrant." The other subsections of §§ 842 and 843 are not so limited. In context, "registrant" is merely a limiting term, indicating that the only "persons" who are subject to these subsections are "registrants." [10] There is no indication that "persons"

[10] This represents a commonsense recognition by Congress that only a registrant could, for example, distribute drugs "not authorized by his registration," § 842 (a) (2), or manufacture substances "not expressly authorized by his registration" or "in excess of [his]

means "nonregistrants" when introducing the other subsections.

There are other indications that § 841, and §§ 842 and 843, do not constitute two discrete systems. Section 843 (b), for example, makes it unlawful for any person to use a communication facility in committing a felony under any provision of the subchapter. But violations of both § 841 and § 843 lead to felony convictions; criminal violations of § 842 are misdemeanors.[11] §§ 842 (c)(2)(A), 802 (13); 18 U. S. C. § 1. And counsel for respondent agreed at oral argument that registrants can be prosecuted under § 841 (a)(2), which prohibits the creation, distribution, dispensing, or possession with intent to distribute or dispense of a "counterfeit substance."

The legislative history indicates that Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant. The penalties now embodied in §§ 841–843 originated in §§ 501–503 of the Controlled Dangerous Substances Act of 1969. The Report of the Senate Judiciary Committee on that bill described § 501 (the counterpart of § 841) as applying to "traffickers." S. Rep. No. 91–613, p. 8

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quota." §§ 842 (b)(1), (2). Nor would there be any reason to apply to nonregistrants the penalties for distributing drugs without complying with the labeling and order-form requirements of the Act, §§ 842 (a)(3), 843 (a)(1), for nonregistrants are barred from making any distributions whatsoever.

[11] Another subsection which can be sensibly interpreted only if it reaches nonregistrants is § 842 (a)(1), which is limited to "any person—who is subject to the requirements of part C." Part C of the Act, §§ 821–829, covers the provisions for registration and applies to "[e]very person who manufactures, distributes, or dispenses any controlled substance or who proposes" to do so. § 822 (a). Presumably, § 842 (a)(1) is so phrased in order to reach those who should have registered but failed to do so.

(1969). Section 502 provided "[a]dditional penalties . . . for those involved in the legitimate drug trade," and "[f]urther penalties . . . for registrants" were specified in § 503. S. Rep. No. 91–613, p. 9. The House Committee Report on the bill that was to become the CSA explains: "The bill provides for control . . . of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal." H. R. Rep. No. 91–1444, p. 3. Although this language is ambiguous, the most sensible interpretation is that the penalty to be imposed for a violation was intended to turn on whether the "transaction" falls within or without legitimate channels. All persons who engage in legitimate transactions must be registered and are subject to penalties under §§ 842 and 843 for "[m]ore or less technical violations." H. R. Rep. No. 91–1444, p. 10. But "severe criminal penalties" were imposed on those, like respondent, who sold drugs, not for legitimate purposes, but "primarily for the profits to be derived therefrom." *Ibid.*

C

Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels. *Id.*, at 6; S. Rep. No. 91–613, p. 4; 116 Cong. Rec. 996 (1970) (remarks of Sen. Dodd). It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic. See *id.*, at 1663 (remarks of Sen. Hruska); *id.*, at 998 (remarks of Sen. Griffin).

Recognizing this concern the Court of Appeals suggested that Dr. Moore could be prosecuted under § 842

(a)(1) for having violated the provisions of § 829 with respect to the issuing of prescriptions.[12] Whether Dr. Moore could have been so prosecuted is not before the

[12] Section 829 provides, in part:

"(a) Schedule II substances.

"Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 353 (b) of this title. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

"(b) Schedule III and IV substances.

"Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 353 (b) of this title. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

"(c) Schedule V substances.

"No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose."

The Attorney General's regulations enacted pursuant to § 829 required:

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of

Court.[13] We note, however, that the penalties for such a violation could hardly have been deemed by Congress to be an appropriate sanction for drug trafficking by a registered physician. Indeed, the penalty for conviction under § 842 would be significantly lighter than, for example, that applicable to a registrant convicted under § 843 for using a suspended registration number.[14] Moreover, a physician who wished to traffic in drugs without threat of criminal prosecution could, if violation of § 829 were the sole basis for prosecution, simply dispense drugs directly without the formality of issuing a prescription. Direct dispensing is exempt from § 829 and thus is not reached by any subsection of § 842 or

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section 309 of the Act (21 U. S. C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 CFR § 306.04 (a) (1973) (redesignated as 21 CFR § 1306.04 (a) (1975)).

The court below suggested that a violation of the "medical purpose" requirement of § 306.04 (a) makes a prescription something other than the "written prescription" required by § 829. The dissent, which agreed that Dr. Moore could be prosecuted under § 842 (a) (1), did not rely on the regulations. It found inherent in the statutory term "prescription" a requirement that the order be issued for a valid medical purpose.

[13] On its face § 829 addresses only the form that a prescription must take. A written prescription is required for Schedule II substances. § 829 (a). Either a written or an oral prescription is adequate for drugs in Schedules III and IV. § 829 (b). The only limitation on the distribution or dispensing of Schedule V drugs is that it be "for a medical purpose." § 829 (c). The medical purpose requirement explicit in subsection (c) could be implicit in subsections (a) and (b). Regulation § 306.04 makes it explicit. But § 829 by its terms does not limit the authority of a practitioner.

[14] In addition, a doctor who dispenses a controlled substance not authorized by his registration to another registrant is also covered by § 842 and would thus be punished as severely as a doctor who sold drugs solely for financial profit to nonregistrants. § 842 (a) (2).

§ 843 so long as the technical requirements are complied with.

But we think it immaterial whether Dr. Moore also could have been prosecuted for his violation of statutory provisions relating to dispensing procedures. There is nothing in the statutory scheme or the legislative history that justifies a conclusion that a registrant who may be prosecuted for the relatively minor offense of violating § 829 is thereby exempted from prosecution under § 841 for the significantly greater offense of acting as a drug "pusher." [15]

III

Respondent argues that even if Congress did not intend to exempt registrants from all prosecutions under § 841, he cannot be prosecuted under that section because the specific conduct for which he was prosecuted was "authorized by [the] subchapter" and thus falls within the express exemption of the section.

The trial judge assumed that a physician's activities are authorized only if they are within the usual course of professional practice. He instructed the jury that it had to find

> "beyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute

[15] Respondent argues that the proper sanction for trafficking physicians is not criminal prosecution, but deregistration or refusal to reregister. But, under respondent's analysis, at the time he was convicted neither penalty could be imposed as a sanction for the conduct in which he engaged. Registration was mandatory for practitioners with state licenses, § 823 (f), and could only be suspended or revoked if the state license was revoked or suspended, if the practitioner had "materially falsified" an application under the Act, or if he had been convicted of a drug-related felony. § 824 (a). Conviction for a misdemeanor under § 842 would be insufficient to support revocation.

> [methadone] by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." App. 123.

The Court of Appeals did not address this argument because it concluded that registrants could not be prosecuted under § 841 under any circumstances. But it suggested that if a registrant could be reached under § 841 he could not be prosecuted merely because his activities fall outside the "usual course of practice." 164 App. D. C., at 322 n. 11, 505 F. 2d, at 429 n. 11.

Under the Harrison Act physicians who departed from the usual course of medical practice were subject to the same penalties as street pushers with no claim to legitimacy. Section 2 of that Act required all persons who sold or prescribed certain drugs to register and to deliver drugs only to persons with federal order forms. The latter requirement did not apply to "the dispensing or distribution of any of the aforesaid drugs to a patient by a physician . . . registered under this Act in the course of his professional practice only." 38 Stat. 786. As noted above, Congress intended the CSA to strengthen rather than to weaken the prior drug laws. There is no indication that Congress intended to eliminate the existing limitation on the exemption given to doctors.[16] The difficulty

[16] The Narcotic Addict Treatment Act of 1974 (NATA), 88 Stat. 124, 21 U. S. C. §§ 802, 823, 824 (1970 ed., Supp. IV), modified the registration and revocation procedures provided in the CSA in order to facilitate "more expeditious" criminal prosecutions by making revocation easier.

There was no indication that Congress thought that trafficking doctors could escape felony prosecution altogether under pre-NATA law. Rather, it sought to "cure the present difficulty in such prosecutions because of the intricate and nearly impossible burden of establishing what is beyond 'the course of professional practice' for

arises because the CSA, unlike the Harrison Act, does not spell out this limitation in unambiguous terms.

Instead of expressly removing from the protection of the Act those physicians who operate beyond the bounds of professional practice, the CSA uses the concept of "registration." Section 822 (b) defines the scope of authorization under the Act in circular terms: "Persons registered . . . under this subchapter . . . are authorized [to dispense controlled substances] . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." But the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his "professional practice."

Registration of physicians and other practitioners [17] is mandatory if the applicant is authorized to dispense drugs or conduct research under the law of the State in which he practices.[18] § 823 (f). In the case of a physi-

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criminal law purposes when such a practitioner speciously claims that the practices in question were ethical and humanitarian in nature." S. Rep. No. 93–192, p. 14 (1973). Dr. Moore's conviction was cited to illustrate that successful criminal actions could be brought only "in the most aggravated of circumstances . . . after prolonged effort to make undercover penetrations." *Id.*, at 13.

[17] "Practitioner" means "a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." § 802 (20).

[18] Under § 823, registration of manufacturers and nonpractitioner distributors (such as suppliers) is discretionary with the Attorney General. He first must make a finding that registration is consistent (in the case of manufacturers of Schedule I and II drugs) or not inconsistent (in the case of manufacturers of Schedule III–V

cian this scheme contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice.[19] The federal registration, which follows automatically, extends no further. It authorizes transactions within "the legitimate distribution chain" and makes all others illegal. H. R. Rep. No. 91–1444, p. 3. Implicit in the registration of a physician is the understanding that he is authorized only to act "as a physician."

This is made explicit in § 802 (20), which provides that "practitioner" means one who is "registered . . . by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." This section defines the term "practitioner" for purposes of the Act. It also describes the type of registration contemplated by the Act. That registration is limited to the dispensing and use of drugs "in the course of professional practice or research."

Other provisions throughout the Act reflect the in-

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drugs and all distributors) with the public interest. In evaluating the public interest the Attorney General is to consider, for example, "maintenance of effective controls against diversion," compliance with applicable state and local law, prior conviction record in drug-related charges, past experience, and (in the case of manufacturers) promotion of technical advances in manufacturing and the development of new substances. Practitioners and pharmacies are automatically entitled to registration to handle drugs in Schedules II–V "if they are authorized to dispense . . . under the law of the State in which they practice." § 823 (f).

[19] The House Report described the rationale behind § 823 (f) as follows: "Practitioners . . . engaged in the distribution chain would be required to be registered, but registration would be as a matter of right where the individual or firm is engaged in *activities* involving these drugs which are authorized or permitted under State law . . . ." H. R. Rep. No. 91–1444, p. 23 (1970) (emphasis added).

tent of Congress to confine authorized medical practice within accepted limits. Section 812 (b)(2) includes in its definition of Schedule II drugs a requirement that "[t]he drug [have] a currently accepted medical use with severe restrictions." Registration under the CSA to dispense or to conduct research with Schedule I drugs, which are defined as having "no currently accepted medical use in treatment in the United States," § 812 (b)(1)(B), does not follow automatically from state registration as it does with respect to drugs in Schedules II through V, all of which have some accepted medical use. § 823 (f). The record and reporting requirements of § 827 are made inapplicable with respect to narcotic drugs in Schedules II through V when they are prescribed or administered "by a practitioner in the lawful course of his professional practice." § 827 (c)(1)(A). Section 828 (a) prohibits the distribution of Schedule I and II drugs unless pursuant to specified order forms; § 828 (e) makes it unlawful for "any person" to obtain drugs with these order forms "for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research." Section 844 (a) prohibits possession of controlled substances unless the drug was obtained "from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized . . . ." See also § 885 (a)(2).

The evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of "professional practice." [20] As detailed above, he gave inadequate physical examinations or none at all.

[20] The jury was instructed that Dr. Moore could not be convicted if he merely made "an honest effort" to prescribe for detoxification in compliance with an accepted standard of medical practice. App. 124.

He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale "pusher"—not as a physician.

IV

Respondent further contended at trial that he was experimenting with a new "blockade" theory of detoxification. The jury did not believe him. Congress understandably was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories. But respondent's interpretation of the Act would go far beyond authorizing legitimate research and experimentation by physicians. It would even compel exemption from the provisions of § 841 of all "registrants," including manufacturers, wholesalers, and pharmacists—in addition to physicians.

In enacting the Comprehensive Drug Abuse Prevention and Control Act of 1970, 84 Stat. 1236, Title II of which is the CSA, Congress faced the problem directly. Because of the potential for abuse it decided that some limits on free experimentation with drugs were necessary. But it was also aware of the concern expressed by the Prettyman Commission:

> "[A] controversy has existed for fifty years over the extent to which narcotic drugs may be administered to an addict solely because he is an addict.
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> . . . . . .
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> "The practicing physician has . . . been confused as to when he may prescribe narcotic drugs for an

> addict. Out of a fear of prosecution many physicians refuse to use narcotics in the treatment of addicts except occasionally in a withdrawal regimen lasting no longer than a few weeks. In most instances they shun addicts as patients." [21]

Congress' solution to this problem is found in § 4 of Title I of the 1970 Act, 42 U. S. C. § 257a. That section requires the Secretary of Health, Education, and Welfare, after consultation with the Attorney General and national addict treatment organizations, to "determine the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction . . . ." It was designed "to clarify for the medical profession . . . the extent to which they may safely go in treating narcotic addicts as patients." H. R. Rep. No. 91–1444, p. 14. Congress pointed out that "criminal prosecutions" in the past had turned on the opinions of federal prosecutors. Under the new Act, "[t]hose physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers . . . ." *Id.*, at 15. The negative implication is that physicians who go beyond approved practice remain subject to serious criminal penalties.

In the case of methadone treatment the limits of approved practice are particularly clear. As Dr. Moore admitted at trial,[22] he was authorized only to dispense methadone for detoxification purposes. His authorization by the FDA to engage in a methadone maintenance program had been revoked. Nor was respondent unfamiliar with the procedures for conducting a legitimate detoxification program. Charges arising

[21] Report of the President's Advisory Commission on Narcotic and Drug Abuse 56–57 (1963), quoted in H. R. Rep. No. 91–1444, pp. 14–15.

[22] App. 101.

out of his 1969 treatment program, which involved a combination of "long term" and "short term" detoxification, were dropped after he testified before a grand jury and agreed to abide by certain medical procedures in future methadone programs. These included obtaining a medical history of each patient, conducting a reasonably thorough physical examination, abiding by the results of urine tests, recording times and amounts of dosages, and either administering the methadone in his office or prescribing no more than a daily dosage.[23] At trial respondent admitted that he had failed to follow these procedures.[24]

V

Respondent argues finally that the statute is sufficiently ambiguous that it must be construed in his favor despite the clear intent of the Congress. It is true that "when choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite." *United States* v. *Universal C. I. T. Credit Corp.*, 344 U. S. 218, 221–222 (1952). In this case, however, the principle set forth in *United States* v. *Brown*, 333 U. S. 18, 25–26 (1948), is appropriately followed:

> "The canon in favor of strict construction [of criminal statutes] is not an inexorable command to override common sense and evident statutory purpose. . . . Nor does it demand that a statute be given the 'narrowest meaning'; it is satisfied if the words are given their fair meaning in accord with the manifest intent of the lawmakers."

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[23] *Id.*, at 97–100, 116, 136–138.

[24] *Id.*, at 97–100.

The judgment of the Court of Appeals is reversed. Because of its disposition of the case, that court did not reach the question whether respondent could be sentenced under 21 U. S. C. § 845, which provides a higher penalty for distribution of controlled substances to persons under 21 years of age. We remand for the sole purpose of considering respondent's claim that he was improperly sentenced under that section.

So ordered.